



Town of Arlington  
Department of Health and Human Services  
Office of the Board of Health  
27 Maple Street Arlington, MA 02476

**Board of Health Meeting Agenda  
Ground Floor Conference Room  
Arlington Senior Center  
Wednesday, May 22, 2019  
5:30 PM**

1. Acceptance of Meeting Minutes from April 10, 2019

2. PRESENTATION:

Arlington High School Club 84

3. HEARING:

Keeping of Hens - 165 Oakland Avenue

4. HEARING:

Tesse Food Products

5. UPDATES:

Environmental

6. UPDATES:

Restaurant

7. UPDATES:

Public Health Nurse

Adjourn



## Town of Arlington, Massachusetts

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### Acceptance of Meeting Minutes from April 10, 2019

#### ATTACHMENTS:

Type	File Name	Description
▣ Reference Material	04102019_Minutes_Board_of_Health_Draft.pdf	Meeting Minutes 4-10-2019



## **Arlington Board of Health Minutes**

Date: *Wednesday, April 10, 2019*

Time: *5:30 pm*

Location: *Arlington Senior Center, 27 Maple Street, Arlington MA 02476 (Mural Room)*

Attendance: Dr. Marie Walsh Condon, Dr. Kevin Fallon, Mr. Kenneth Kohlberg

Staff in Attendance: Natasha Waden, Public Health Director; Pat Martin, Health Compliance Officer; Kylee Sullivan, Health Compliance Officer; Jessica Kerr, Public Health Nurse

Others in Attendance: D.J. Wilson, Mass Municipal Association; Adam Kurowski, Town of Arlington I.T. Department; Mr. John Kozma

Recording Secretary: Laura Munsey, Office Manager, Health and Human Services

### **Minutes**

Meeting called to order by Dr. Marie Walsh Condon at 5:38 pm

#### **1. Acceptance of Meeting Minutes from February 6, 2019**

Motion Made by Dr. Kevin Fallon, seconded by Mr. Kenneth Kohlberg to accept the February 6, 2019 meeting minutes as submitted.

Vote: 3-0 in favor of the motion (Unanimous)

#### **2. Correspondence Received: Lester J. Hartman, MD**

Inspector Pat Martin informed the Board that the Health Department received 2 emails from Lester Hartman, MD on February 2, 2019 and March 15, 2019 regarding his involvement in the Tobacco 21 Campaign and related legislation. Mr. Martin read the correspondence aloud. Included with the second email were 3 attachments:

- Massachusetts Flavor Restriction Map
- Research Article regarding Menthol cigarettes and the public health standard: a systematic review
- Effects of Nicotine and Mint/Menthol on Genes and Disease Risks

Copies of the attachments were provided to the Board.

### 3. Discussion: Tobacco Update – D.J. Wilson

Director Waden introduced Mr. D.J. Wilson of the Massachusetts Municipal Association. Mr. Wilson provided a hand out to the Board: Municipal Tobacco Control Technical Assistance Programs' Local Policies Restricting Flavored "Other Tobacco Products" (OTP) to Adult-Only Retailers.

Mr. Wilson informed the Board that several communities are researching restrictions similar to the ones which Somerville recently added to their tobacco regulation. The amendments to Somerville's regulation include:

- Removing menthol, mint, and wintergreen from the exempted section of the characterizing flavor definition and moving it to the list of flavors that are considered flavored tobacco
- Limiting the sale of e-cigarettes to adult-only retail tobacco stores
- Re-categorizing tobacco as a flavored product for e-cigarettes

Needham, Ashland, and Malden have updated their tobacco regulations to include sections of Somerville's amendments. Several other communities are contemplating the addition of similar restrictions to their regulations. The Town of Brookline is currently considering a warrant article to ban flavored tobacco from all tobacco retailers. Mr. Wilson informed the Board that Somerville's amendments are facing legal challenge.

Currently, Arlington's tobacco regulation includes a basic cap based on population density. Mr. Wilson explained that the Town could consider including an advanced cap which would allow for the maximum number of permits to be reduced when a retailer stops selling tobacco and returns their permit. A dual cap may also be considered with either a basic or an advanced cap.

Mr. Wilson presented options for the Board to consider:

1. Amend nicotine and tobacco product definitions regardless of nicotine content. Mr. Wilson added that the State and the Attorney General's Office include vape pens in the definitions.
2. Amend the cigar sales section to include updated language.
3. Include the regulation of CBD in the Town's tobacco regulations. As an example, Mr. Wilson informed the Board that Medford limited the sale of CBD to adult-only establishments. Mr. Wilson discussed the lack of regulation for CBD. At the state level, the Department of Agricultural Resources is tasked with regulating CBD cultivation, production, and sale. However,

the implementation of such regulations is still in the works. Public health concerns related to CBD include issues of quality control, particularly assessing and confirming purity and strength.

Director Waden recommends the Staff review current regulations to make appropriate updates due to the fluid and rapidly changing nature of vaping products. Mr. Wilson stated that menthol is often what principals are finding in schools. Kenneth Kohlberg expressed concern that the Arlington Board of Health is being asked by Dr. Hartman to implement a regulation similar to the regulation in Somerville for which they are being sued. Mr. Wilson stated that, in Somerville, retailers didn't seek an injunction but asked the courts to set the case aside on the grounds that the regulations are arbitrary and capricious. Somerville Board of Health members were named individually in the law suit. Other communities have pushed the start date out to see how the Somerville case is resolved.

The Board thanked D.J. Wilson for his informative presentation. The Board requested some additional information and will look into capping establishments.

4. Discussion: Novus Agenda – Adam Kurowski. Adam Kurowski thanked the Board for considering the implementation of Novus Agenda. The Board of Health is the 4<sup>th</sup> Board in Town to explore Novus Agenda. Mr. Kurowski led an interactive demonstration of the program with the Board. Benefits of Novus Agenda were discussed such as the creation of a database that is keyword searchable. This is particularly helpful for Public Record Requests received by the Department. Novus Agenda is easy to use during Board meetings and also is available for research and preparation work before meetings, especially because users can add notes to agenda items. Mr. Kurowski explained that another benefit of the program is that the public can access the uploaded documents on the program as well. Mr. Kurowski stated there are 2 steps remaining. The steps are: 1) ensure all Board members and Department Staff are trained in using the program and 2) input minutes within the program itself. Mr. Kurowski explained that the Board can use the program on any device, including their personal computers, laptops, or tablets. This is because software is not installed, but rather the program is website-based. It was recommended that the Health consider uploading regulations to the database. Ken Kohlberg stated that he likes getting paper copies of the packets, to which the rest of the Board agreed. It was decided that the Board will continue to receive paper packets as long as needed or requested.

Mr. Kurowski presented the following questions to the Board:

1. Should the public facing search tool be added to new agenda packets uploaded to the website?  
The Board agreed they would like to do that. The packets would be embedded on the website, and a calendar message would link to the agenda page.
2. Should accepted meeting minutes be published through Novus Agenda?  
The Board agreed they would like to do that as well.

3. Would the Board like to continue to explore using Novus Agenda during the meetings with Mr. Kurowski available for guidance?

The Board also agreed to this.

Mr. Kurowski will work with Director Waden and send additional information. The Board stated they would like to use Novus Agenda on different types of electronic devices in future meetings. The Board thanked Mr. Kurowski for his assistance and expertise regarding this transition to Novus Agenda.

5. Hearing: Keeping of Hens – 4 Alpine Street. Inspector Sullivan informed the Board that a site plan review application was submitted for the Keeping of Hens by 4 Alpine Street property owner, John Kozma. She reported everything was complete and all requirements were met. Inspector Sullivan conducted a site walk and inspected the proposed coop location, compost location, and feed storage area. She did not observe any issues during her visit. One of the property abutters recently passed away, and the applicant reached out to the estate. Inspector Sullivan reported that sufficient notification was provided. The applicant reported that he completed a hen keeping course through Arlington Community Education. The course covered how to store food, make the pen area predator proof, and keep the hens healthy and dry in the winter. Inspector Sullivan stated that the instructor at Arlington Community Education reached out to the Health Department and tailored the course to the Arlington Hen Bylaw.

Motion: Made by Kevin Fallon, Seconded by Kenneth Kohlberg to approve the keeping of hens permit at 4 Alpine Street in Arlington contingent upon final construction of coop and final inspection by the Health Department.

Vote: 3-0 in favor of the motion (Unanimous)

6. Hearing: Microblading. The applicant withdrew her variance request. As a result, no further action is required at this time.

7. Hearing: Regulation of the Arlington Board of Health Restricting the Sale of Medical Marijuana. Inspector Martin recommended the following housekeeping item: amend the regulation to include the incorporation of 935 CMR 501.000. This will allow Department Staff to enforce both local regulations and also state regulations.

Motion: Made by Dr. Kevin Fallon, Seconded by Mr. Kenneth Kohlberg to update the Regulations Restricting the Sale of Medical Marijuana as recommended by the Health Department.

Vote: 3-0 in favor of the motion (unanimous)

Director Waden discussed with the Board the process of applying for an Adult-Use Marijuana Establishment Permit. She stated interested applicants must have a community host agreement in place. Currently, Doug Heim, Town Counsel, is creating a step by step process for this as many Departments are involved in the permitting of such an establishment. Director Waden stated that several residents attended a recent Select Board Meeting to express concern about Adult-Use Marijuana. She reported that Mass Patient Foundation is attempting to amend their community host agreement to change their dispensary location, and expand their establishment to adult-use recreational as well. Zoning caps for Adult-Use Marijuana Establishments are currently at 3 but there is the potential to have 3 recreational and unlimited medical establishments in Town.

8. Updates:

19 Beck Road – Basement. Inspector Martin informed the Board this basement apartment has been disassembled after the Building Department inspected the dwelling and required the removal of several kitchen elements. Inspector Martin stated that presently no one is living in basement and the owner is aware that it is an uninhabitable space. All other housing code violations have been brought into compliance.

9. Updates:

Environmental. Inspector Sullivan informed the Board that spring permits renewals for the keeping of hens have been sent to residents. She also stated that applications for camps, pools, and bathing beaches are being updated and will be available to the public soon. Inspector Sullivan stated there are rodent concerns at two elementary schools including Dallin and Stratton. Dry ice was implemented, and upon recent inspection the treatments appear successful. Inspector Sullivan discussed that it is important to eliminate all food sources for rodent control. Inspector updated the Board on her work with the Attorney General's Abandoned Housing Initiative (AHI). 27 Hopkins Street has recently been sold and all violations have been brought into compliance. Currently, the Town is working with the AHI on 1530 Mass Ave and 44 Rublee Street.

10. Updates:

Restaurant Updates. Inspector Martin informed the Board:

- 2 new establishments have opened: USushi Café and Bubble Nation
- There have been no new closures
- There are 6 open plan reviews
- The Department has signed off on a waiver for pest control at the Gibbs School

11. Updates:

Public Health Nurse Updates. Jessica Kerr informed the Board of an incident regarding a 5 and 7 year old in an after school program at the Gibbs School that got stuck with a needle the end of March. One student stuck herself with the needle, and the other helped out and subsequently stuck herself. Both children were brought to Winchester Hospital. The needle was kept and will be tested. This incident brings to light a growing problem with IV drug use. In response to the incident, all schools educated students about what to do in similar situations. After school programs are speaking with their students as well. Nurse Kerr stated there are no updates on the two students but when she last heard, they were well and healthy. It was reported that schools are conducting sweeps of the property and outside grounds.

Nurse Kerr also reported that the MRC is hosting training in May. At the training there will be three speakers, one of which is the MRC leader who helped during the gas explosions in Andover.

Meeting adjourned at 7:18 pm

Next meeting is scheduled for May 22, 2019 at 5:30 pm





## Town of Arlington, Massachusetts

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### Keeping of Hens - 165 Oakland Avenue

#### ATTACHMENTS:

	Type	File Name	Description
▢	Reference Material	165_Oakland_Ave_Hens.pdf	165 Oakland Ave Hens



Town of Arlington  
Department of Health and Human Services  
Office of the Board of Health  
27 Maple Street  
Arlington, MA 02476

Tel: (781) 316-3170  
Fax: (781) 316-3175

**MEMO**

To: Board of Health Members  
From: Kylee Sullivan, Health Compliance Officer  
Date: May 16, 2019  
RE: Keeping of Hens Request at 165 Oakland Avenue

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Jay Brewer submitted a Keeping of Hens Site Plan Review Application for 4 Alpine Street on April 10, 2019. The property's dwelling is a single-family structure owned by the applicant. The property owner plans to keep four hens on this 7275 Sq Ft lot near the Dallin School. The property has four abutters. Abutters were notified by the applicant of his intent to keep hens via certified mail. The letters notified the abutters of a Board of Health hearing to be held on May 22, 2019 at 5:30pm. To date, one neighbor inquired about odors resulting from the hens; the neighbor was informed that there are daily and weekly maintenance plans to prevent odors and other nuisances.

The attached site plan provided by the applicant illustrates that all distance requirements set forth in the Town Bylaw are satisfied; the coop's proposed location does not violate the six feet minimum distance from all property lines. The materials submitted included all necessary components of the site plan application. A site walk was conducted on April 30, 2019 to verify the proposed location of the coop/pen and the structure.

Please note, the proposed size of the chicken run (24 Sq Ft) would allow a maximum four hens to be kept in order to comply with the Bylaw's requirement of 5 Sq Ft per hen in the run. Mr. Brewer is aware of this and understands that if he wants to keep more than four hens in the future he will have to enlarge the run and receive approval from the Board.

If this application is approved, no final permit will be granted until an inspection of the finished coop confirms the build-out matches the design specifications.

## 165 Oakland Avenue – Site Visit Diagram





DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF THE BOARD OF HEALTH

Town of Arlington

27 Maple Street  
Arlington, Massachusetts 02476

## KEEPING OF HENS SITE PLAN REVIEW APPLICATION

*These guidelines are not final requirements. The Board of Health may require additional information based on the type and location of operation.*

Plan Review Fee: \$150.00 (checks made payable to: Town of Arlington)

For office use only: Date/time application received: 4/10/2019 Received by: KS  
(BOH Staff)

APPLICANT NAME: Jay Brewer

APPLICANT ADDRESS: 165 Oakland Ave Arlington MA 02476

CONTACT NUMBER: 857 928 7513

CONTACT EMAIL: jay@jaybrewer.net

### Keeping of Hens Application Process Summary

1. Submit this Site Plan Review Application to Health Department with check for \$150.
2. Health Department reviews application and conducts site walk.
3. After plan review and site walk, a meeting date with the Board of Health is set. The applicant will notify all abutters at least 14 days but no more than 30 days prior to the hearing, of their intent to keep hens and the BOH hearing date, time and location. Abutters shall include both owners and tenants. The applicant shall provide verification of notification in the form of a signed letter or USPS receipt that a certified letter has been received.
4. A meeting with the Board of Health is held and a decision made to approve or deny application based upon all requirements set forth in town bylaw.
5. Once approved by the Board of Health, the applicant is required to submit an Application for Annual Permit to Keep Hens to the Health Department with a check for \$100 and the applicant will be permitted to construct coop and pen.
6. A final inspection is conducted once coop and pen have been constructed and final approval to keep hens is granted.
7. An annual permit to keep hens is required through the Health Department expiring April 1st of every year. A renewal permit must be obtained. Permit holders that fail to renew their keeping of hens permit prior to April 1<sup>st</sup> are subject to a \$100 reinstatement fee.
8. An annual inspection will be conducted by the Health Department. Failure to meet requirements set forth in the town bylaws may result in a re-inspection fee of \$100 and a hearing with the Board of Health to determine whether permit should be revoked, suspended, or subject to further conditions.

**CIRCLE/ANSWER THE FOLLOWING QUESTIONS:**

Is the applicant the sole owner of the property where hens will be kept?

YES/NO

If no, please provide signed written statements from all property owners granting permission for the keeping of hens.

What is the size of the property lot in square feet?

7275 sq ft

**I. HENHOUSE / PEN:**

**1. Location**

a. Will the henhouse/pen enclosure be in the rear yard of the property?

YES/NO

b. Will the henhouse/pen enclosure be at least six (6) feet from all property lines?

YES/NO

c. Will the henhouse/pen enclosure be at least 25 feet from existing residences on adjacent lots?

YES/NO

d. Will the henhouse/pen enclosure be located at least 200 feet from the high water mark of any known source of drinking water supply or any tributary thereof, and at least 50 feet from any well?

YES/NO

e. Will the henhouse/pen enclosure conform to all relevant property setbacks for accessory structures as specified in sections 6.18 and 8.23 of the zoning bylaws?

YES/NO

f. Will the henhouse/pen enclosure interfere with any utility or other feature of the property that needs suitable access?

YES/NO

g. Will the henhouse/pen enclosure be located in a well-drained area that does not discharge to a public way or neighbor's property?

YES/NO

h. Please provide a certified plot plan depicting all of the following: all structures on property, all structures on abutting properties, and proposed locations of the henhouse/pen enclosure, composting/manure storage and food storage.

**2. Construction**

a. Will the henhouse enclosure provide a minimum interior floor surface of at least two (2) square feet per bird?

YES/NO

b. Will the pen enclosure provide a minimum ground surface of at least five (5) square feet per bird?

YES/NO

c. Will the henhouse/pen enclosure be securely constructed in a manner that excludes predators and pests, including those that fly, burrow and reach?

YES/NO

## II. HENS:

### 1. Hen keeper

a. Will the hen keeper be taking, or has the hen keeper taken, a class in keeping hens? YES/NO  
If yes, please provide a copy of a certificate of completion from a hen-keeping course.

b. Will there be a knowledgeable person in charge to care for hens during vacations or extended leaves? YES/NO

### 2. Source

a. What type of hens and how many hens will you be keeping?

We will be keeping 4 hens. They will be of the Barred Rock variety.

b. Will the hens be acquired from S. pullorum clean sources from National Poultry Improvement Plan (NPIP) participants? YES/NO

c. Where will the hens be acquired from and what documentation will be provided?

The hens will be acquired from Meyer Hatchery and they can provide a NPIP certificate.

### 3. Health & Disease Concerns

a. Will the hens be vaccinated from any communicable diseases? YES/NO  
If yes, from what? Mareks Disease

b. Will newly acquired hens be isolated from healthy resident birds? YES/NO  
If yes, where and for how long? We have no resident birds

c. Will the hens be separated from wild migratory fowl at all times? YES/NO

d. What will be done with a hen if it dies? We will wrap it and dispose of it through the garbage.

- d. Will the pen enclosure have a predator and pest proof material across the top? ☒ YES ☐ NO
- e. Will the henhouse provide protection from the elements as needed? ☒ YES ☐ NO
- f. Will the henhouse be constructed in such a manner and with such materials that allow for effective weekly cleaning? ☒ YES ☐ NO
- g. Please provide a separate detailed description of the henhouse/ pen enclosure, including square footages and photographs if possible.

### 3. Maintenance

- a. Will the feed be securely stored in a rodent and pest proof container? ☒ YES ☐ NO
- b. Will the feed leftover from feeding remain in an area accessible to rodents and pests past dusk? ☒ YES ☐ NO
- c. If weather is too cold, or composting is otherwise not possible, will there be a sealable container for waste to be stored until disposal? ☒ YES ☐ NO
- d. If composting is possible, how and where will waste be composted with carbonaceous material such as hay, bedding, or leaves? Please identify composting/ manure storage location on required certified plot plan.

We plan to compost overflow waste material in  
our preexisting compost bin marked on the plan.  
It already contains food waste.

- e. What measures will be taken to prevent the buildup of pests or rodent populations due to the presence of hens on the property?

Feed will be stored in sealed containers and  
coop will be cleaned regularly as to avoid  
the build up of waste material or leftover  
food that might promote an increase in  
a pest or rodent population.

- f. Please provide a separate detailed written maintenance plan describing the following: cleaning practices and schedule for the henhouse/pen enclosure and feed and water containers, which anti-bacterial/viral cleaning solution will be used, which bedding material will be used in the henhouse and at which depth it will be provided, how frequently the bedding material will be composted, and any other appropriate nuisance (odor & noise) prevention measures that will be taken.

**To complete this application the following materials must be provided:**

- Copy of list of property abutters obtained from Town of Arlington Assessors Office
- If applicant is not sole property owner, signed written statements from all property owners granting permission for the keeping of hens
- Plot plan drawn to scale depicting all of the following: all structures on property, all structures on abutting properties, proposed locations of the henhouse/pen enclosure, composting/manure storage and food storage, and distance of henhouse and pen from property lines and existing adjacent residences. The BOH reserves the right to require the applicant to provide a plot plan certified by a professional engineer or land surveyor to resolve any questions or disputes relating to the conformance of the placement of the henhouse and pen with any and all relevant property setbacks and zoning bylaw requirements.
- Written maintenance plan and description of henhouse/pen enclosure
- Copy of certificate of completion from a hen-keeping course if applicable
- After a BOH hearing date has been set, submit a copy of signed letter or receipt from USPS that a certified letter has been received by each abutter informing them of your application to keep hens and notifying them of the BOH hearing date, time and location. Abutters include both property owners and tenants.

I have read the town bylaws regarding the keeping of hens and understand the requirements as outlined. I understand failure to comply with the requirements of the town bylaws and failure to prevent a public health nuisance may result in revocation of my Permit to Keep Hens.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

-----Office use only-----

Board of Health Meeting Date Assigned: \_\_\_\_\_



Our Coop is from Mark King or King's Berry Farm  
123 North Brookfield Road  
East Brookfield, MA 01515  
PH: 774-452-211

It is a 4 X 8 COOP

Coop sized for up to 8 chickens with forest green roof.

Overall dimensions are 4' wide x 8' long x 8' high with a 12 sq. ft. hen house and a 24 sq. ft. chicken run area.

It features a cloth wire chicken run.



Additional options are the following:

Plastic hen house floor.....

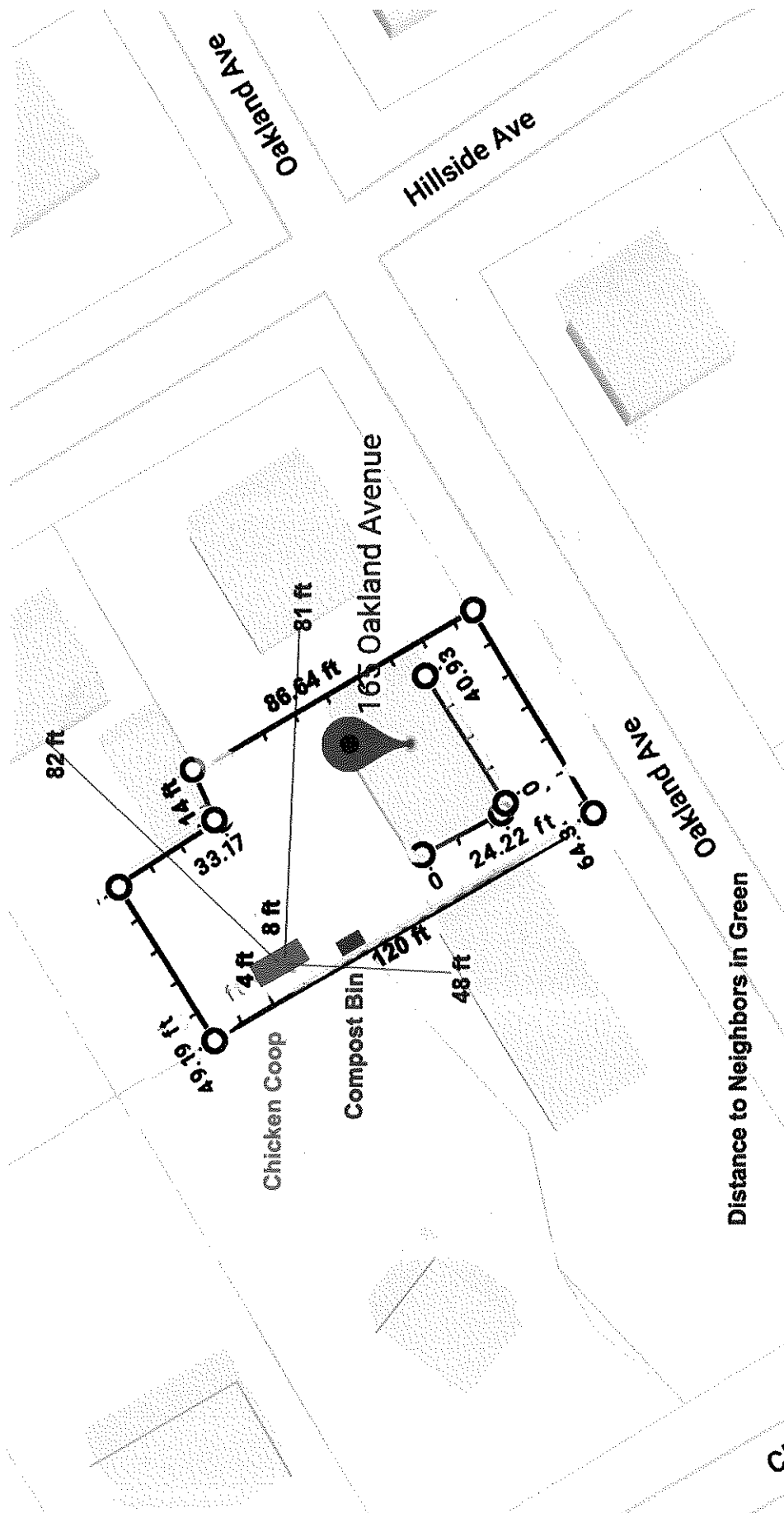
Storage Cabinet to deter pests

Our address is:

Jay Brewer  
165 Oakland Avenue  
Arlington, MA 02476  
Phone: 8579287513

### Chicken Maintenance Plan

We will feed and water the chickens daily, taking the food out at night so as not to attract rodents. The coop will be cleaned every weekend, with spot cleaning as necessary throughout the week. Spot cleaning consists of removing any visibly soiled bedding and changing the nest boxes bedding as well. The weekly deep cleanings will consist of changing all bedding, hosing down the interior completely, and applying liberal amounts of vinegar as a cleaner, as well as a chicken safe antibacterial. We will also clean the feeder and waterer. The coop will use pine shavings as bedding and the bedding will be about 1-2 inches thick. The chicken breed we are purchasing is known for being quiet and cold hardy, and so will reduce noise concerns.





Office of the  
Board of Assessors  
Robbins Memorial Town Hall  
Arlington, MA 02476  
(781) 316-3050  
Assessors@town.arlington.ma.us

**Abutters List**

Date: April 08, 2019

Subject Property Address: 165 OAKLAND AVE Arlington, MA  
Subject Property ID: 160-3-10

Search Distance: Direct Abutters-Keeping of Hens

The Board of Assessors certifies the names and addresses of requested parties in interest, all abutters to a single parcel who are direct abutters

*Kevin L. Feeley*  
*Robert E. Greeley*  
*[Signature]*

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**Board of Assessors**

**Abutters List**

Date: April 08, 2019

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Prop ID: 160-3-11.A  
Prop Location: 169 OAKLAND AVE Arlington, MA  
Owner: WOLFF MARY K/ LIFE ESTATE  
Co-Owner: MARY K WOLFF LIVING TRUST  
Mailing Address:  
169 OAKLAND AVENUE  
ARLINGTON, MA 02476

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Prop ID: 160-3-12.A  
Prop Location: 122 CLAREMONT AVE Arlington, MA  
Owner: BACHMANN MATTHEW J &  
Co-Owner: MUISE KIMBERLY A  
Mailing Address:  
122 CLAREMONT AVE  
ARLINGTON, MA 02476

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Prop ID: 160-3-8  
Prop Location: 125 HILLSIDE AVE Arlington, MA  
Owner: CHRISTIE CHADWICK  
Co-Owner: CHRISTIE SARAH  
Mailing Address:  
125 HILLSIDE AVE  
ARLINGTON, MA 02476

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Prop ID: 160-3-9  
Prop Location: 129 HILLSIDE AVE Arlington, MA  
Owner: LIBBY MICHAEL & EMILY  
Co-Owner:  
Mailing Address:  
129 HILLSIDE AVE  
ARLINGTON, MA 02476

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Prop ID: 160-3-10  
Prop Location: 165 OAKLAND AVE Arlington, MA  
Owner: BREWER JAY  
Co-Owner: BAZAR MAYA  
Mailing Address:  
165 OAKLAND AVE  
ARLINGTON MA 02476



This data shown on this map are provided for informational and planning purposes only. The Town and its consultants are not responsible for the misuses or misrepresentation of the data.



- Places by Category**
- Police Station
  - Fire Station
  - School
  - Public Works
  - Parking
  - Parcel Map - Misc (traffic)
  - Recreation - Facilities
  - Recreation - Fields Courts
  - Recreation - Fields Courts
  - Open Space - Conservation
  - Open Space - Minuteman
  - Open Space - Labels
  - Open Space
  - Open, State or Private
  - Parcel
  - Other Town Owned
  - Buildings
  - MA Highways
  - Interstate
  - US Highway
  - Norwood Routes
  - Town Boundary
  - Abutting Towns
  - Roads - OneWay (for Base)
  - Roads - For Small Scale (1:10,000)
  - Local Road
  - Canalway - Roads
  - Road1
  - Road2
  - Road3
  - Road4
  - Pavement Markings
  - Impervious Surface
  - Street
  - Sidewalk
  - Other Surfaces
  - Water Line
  - Water Body

0 130 260 ft

Printed on 04/08/2019 at 09:53 AM

Jay Brewer  
165 Oakland Avenue  
Arlington, MA 02476

April 25, 2019

Dear Neighbor,

We're writing this letter to inform you we (Maya, Jay, Anya, and Ewan) are applying for a permit to have chickens for pets at 165 Oakland Avenue this Spring.

We're letting you know so that if you have any concerns you can call us at 857-928-7513 or email [jay@jaybrewer.net](mailto:jay@jaybrewer.net). You can also attend the Board of Health Meeting on May 22nd at 530 pm in the Senior Center ground floor mural room (27 Maple Street) when our application is set to be reviewed.

We have submitted our application for review and intend to have 4 chickens with a small coop. We have also submitted our maintenance plan, and will have a site review prior to the above meeting.

A couple of things to note:

- We can only have hens - so no roosters will be making pesky loud noises in the early hours of the morning
- We will keep things clean and tidy and compost and dispose of all waste properly
- We will abide by all the setback laws and have the coop the proper distance from the property lines - this is part of the site review by the town
- We have also recently updated the fence so that there is no issues if they do escape but the hens can not be free range and will stay in their coop at all times
- We're excited to have you meet the chickens once they're here, and would love to invite you to meet them, as well as fresh eggs once the chickens are old enough to lay.

Again please let us know if you have any questions. This letter has been sent certified because of the requirements of the application per the town bylaws and to acknowledge and make sure you have been informed.

Thank you!

- Jay, Maya, Anya, and Ewan Brewer

**From:** Jay Brewer <jay@jaybrewer.net>  
**To:** Kylee Sullivan <KSullivan@town.arlington.ma.us>  
**Date:** 04/27/2019 05:15 PM  
**Subject:** Re: Keeping of Hens Plan Review Application

Here are all 4 of our certified receipts for the chickens to out abutting neighbors

Go Chicken Coop Letters

5:12 ↵



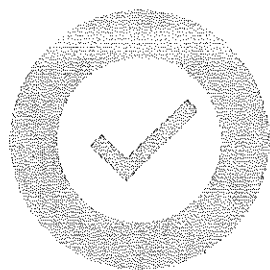
## USPS Tracking®

April 27, 2019 at 3:51 pm

### Expected Delivery on:

On Time:

Saturday, April 27, 2019 by  
8:00pm



70181830000150482747

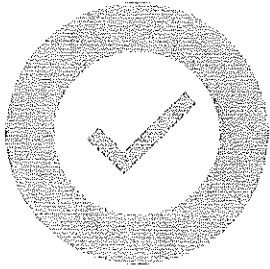
### Delivered:

ARLINGTON, MA 02476 on  
April 27, 2019 at 4:00 pm

### Expected Delivery by:

Saturday, April 27, 2019 by  
8:00pm



**70181830000150482723****Delivered:**

ARLINGTON, MA 02476 on  
April 26, 2019 at 3:27 pm

**Expected Delivery on:**

Friday, April 26, 2019 by  
8:00pm

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**70181830000150482730****Delivered:**

ARLINGTON, MA 02476 on  
April 26, 2019 at 9:13 am

**Expected Delivery on:**

Friday, April 26, 2019 by  
8:00pm

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Last Refreshed: 4/26/2019 4:04 PM



## Town of Arlington, Massachusetts

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### Tesse Food Products

#### ATTACHMENTS:

	Type	File Name	Description
▢	Reference Material	Tesse_Memo_5-16-2019.pdf	Tesse Memo
▢	Reference Material	TESSE_CEASE_and_DESIST.pdf	Cease and Desist
▢	Reference Material	Tesse_Hearing_Request.pdf	Tesse Hearing Request
▢	Reference Material	FDA_CBD_Press_Releases.pdf	FDA CBD Press Release
▢	Reference Material	MDAR_Hemp_Policy.pdf	MDAR CBD Hemp Policy



Town of Arlington  
Department of Health and Human Services  
Office of the Board of Health

27 Maple Street  
Arlington, MA 02476

Tel: (781) 316-3170  
Fax: (781) 316-3175

**MEMO**

To: Board of Health Members  
From: Pdraig Martin, Lead Health Compliance Officer  
Date: May 16, 2019  
RE: Tesse Hearing

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Recently, another community reached out to our department regarding the use of cannabidiol (CBD) at Tesse Food Products, LLC which operates out of the Local Fare, at 2 Lake Street, Arlington MA. After reviewing their file, it became clear that the two products they produce do contain full spectrum hemp oil containing CBD. The FDA considers CBD to be an unapproved food additive, and its use is a violation of the 2013 FDA Food Code and Chapter X of the State Sanitary Code, 105 CMR 590.000. The permit materials submitted to the Health Department by Tesse Products, LLC were accurate, and its approval was an oversight by the department. Nyree Bekarian Mack, co-owner of Tesse Food Products, was notified via telephone on February 14, 2019 that the use of CBD is prohibited and that they could no longer use it in their products. An official Cease and Desist letter was issued on February 28, 2019.

In addition to the above information, the Massachusetts Department of Agriculture Resources (MDAR) requires industrial hemp to come from a licensed Massachusetts grower. MDAR also requires licenses for processors, which includes manufacturers of edible CBD products as well as retailers of CBD products intended for human consumption. Tesse Food Products, LLC did not obtain their CBD from a licensed in-state grower and also did not have the required MDAR licenses for manufacturing and retail.

**Background information:**

Below is a summary of the policies and information available to the department at this time.

**(Massachusetts)**

On July 28, 2017, Gov. Baker signed H. 3818, An Act to Ensure Safe Access to Marijuana, which updated the Commonwealth's laws governing the use of marijuana. This legislation also created a distinction between marijuana, hemp and industrial hemp, allowing hemp to be grown commercially as industrial hemp or as part of an Agricultural Pilot Program. As such, in accordance with Sections 116 through 123 of M.G.L. c. 128, the MDAR has the authority to oversee hemp and industrial hemp within the Commonwealth. As outlined in MDAR's Interim Policy for the Commercial Industrial Hemp Program (April 30, 2018) the following is required:

- CBD produced for use in food must come from a Massachusetts licensed grower. All products produced by a MDAR licensed grower must be tested by an approved Massachusetts laboratory to determine that the THC and pesticide levels are within MDAR's standards.
- Processors can only acquire industrial hemp from a licensed MA grower and must also be licensed by MDAR. Processors can fall into two categories:

Extractors - If an extractor is using the crop for human consumption, the finished extraction must be tested to determine its cannabinoid profile.

Manufacturers - Under MDAR's policy, establishments preparing prepackaged edible CBD products are considered manufacturers. Responsibilities for manufacturers include (but are not limited to): receiving extracted product from a MA licensed extractor, maintaining records for the extracted product, maintaining records for its end product, and meeting specific labeling requirements.

- In addition to these requirements, establishments selling food products containing CBD must have a retail license from MDAR. This pertains to both prepackaged items as well as food prepared for onsite consumption.
- In a conversation with Sarah Gorbin, MDAR Hemp Program Coordinator on March 20<sup>th</sup>, it was reported that MDAR has issued 13 licenses to growers and processors and currently has approximately 60 pending applications. To date, MDAR has not issued any retail permits for the sale of food products containing CBD. As of the March 20<sup>th</sup>, Tesse Products, LLC (DBA Tesse) was not identified as one of the 13 licensed growers/processors.

**(Federal)**

- In 2018 the Agriculture Improvement Act of 2018 was signed into law removing hemp from the Controlled Substances Act, and therefore it is no longer an illegal substance under federal law. However, Congress preserved FDA authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act.
- At this time the FDA has evaluated and determined that hulled hemp seeds, hemp seed protein and hemp seed oil are the only parts of a hemp plant that are considered to be Generally Recognized as Safe (GRAS) products. Therefore, those products only, can be legally marketed in human foods for use without food additive approval, provided they comply with all other requirements and do not make disease treatment claims.
- Tesse Products LLC, labels their products as “Full-Spectrum Hemp Extract”

**Attached please find the following documents:**

1. Cease and Desist letter
2. Tesse hearing request
3. Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds
4. MDAR Interim Policy – Commercial Industrial Hemp Program



Town of Arlington  
Department of Health and Human Services  
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**ORDER TO CEASE AND DESIST**

February 28, 2019

Sent via Email: [nyreel@gmail.com](mailto:nyreel@gmail.com)

Tesse Products, LLC  
Attn: Nyree Bekarian Mack  
66 Newport Street  
Arlington, MA 02476

**RE:** *Full Spectrum Hemp Oil containing cannabidiol (CBD)/ Unapproved Food Additive*

Dear Ms. Bekarian Mack:

Please be advised, it has recently come to the attention of the Board of Health that your establishment, Tesse Products LLC, which operates out of the Local Fare, at 2 Lake Street, Arlington MA is producing food products infused with full spectrum hemp oil containing cannabidiol (CBD). Specifically, the food products have been identified as Turmeric & Ginger Tahini Bites and Sesame & Honey Tahini Bites.

**VIOLATION**

In accordance with the FDA 2013 Food Code and Chapter X of the State Sanitary Code, 105 CMR 590.000: CBD is considered an unapproved food additive. In accordance with Food Code 3-202.12: "Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170-180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186, substances that exceed amounts specified in 9 CFR Subpart C Section 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR 180 Tolerances for pesticides chemicals in food, and exceptions."

**ORDER**

As a result, You are hereby ordered to **CEASE and DESIST the use of full spectrum hemp oil containing CBD immediately.** Failure to do so may result in a hearing with the Board of Health and or suspension or revocation of your permit to Operate a Food Establishment. Please be advised you have the right to request a hearing with the Board of Health. Said request must be in writing, addressed to the Board of Health, and received within 10 days of receipt of this notice.

Questions regarding this matter may be directed to this office at 781-316-3170.

Sincerely,

A handwritten signature in black ink, appearing to read "Padraig Martin", is written over a horizontal line.

Padraig Martin  
Health Compliance Officer  
781-316-3169  
[pmartin@town.arlington.ma.us](mailto:pmartin@town.arlington.ma.us)

cc: Natasha Waden, Director of Public Health  
The Local Fare

3/7/2019

Arlington Board of Health  
27 Maple St.  
Arlington, MA 02476

RE: Hearing Request

Dear Arlington Board of Health:

In reference to a Cease and Desist order I received on February 28, 2019 for use of full spectrum hemp extract at The Local Fare, I would like to request a hearing with the Arlington Board of Health.

Sincerely,



Nyree Bekarian Mack  
Tesse Goods

66 NEWPORT ST ARLINGTON, MA 02476  
T 510-684-0046

Health & Human Services

MAR 11 2019

Arlington, MA

# Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds

## For Immediate Release

December 20, 2018

### Statement

Today, the Agriculture Improvement Act of 2018 was signed into law. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (*Cannabis sativa* L.), and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). These changes include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law.

Just as important for the FDA and our commitment to protect and promote the public health is what the law *didn't* change: Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows the FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds.

We're aware of the growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD). This increasing public interest in these products makes it even more important with the passage of this law for the FDA to clarify its regulatory authority over these products. In short, we treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of the source of the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act. To help members of the public understand how the FDA's requirements apply to these products, the FDA has maintained a [webpage](#) with answers to frequently asked questions, which we intend to update moving forward to address questions regarding the Agriculture Improvement Act and regulation of these products generally.

In view of the proliferation of products containing cannabis or cannabis-derived substances, the FDA will advance new steps to better define our public health obligations in this area. We'll also continue to closely scrutinize products that could pose risks to consumers. Where we believe consumers are being put at risk, the FDA will warn consumers and take enforcement actions.

In particular, we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds. Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its

intended use before it may be introduced into interstate commerce. This is the same standard to which we hold any product marketed as a drug for human or animal use. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.

Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.

We'll take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and are being marketed in violation of the FDA's authorities. The FDA has sent [warning letters](#) in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. The FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient.

These pathways include ways for companies to seek approval from the FDA to market with therapeutic claims a human or animal drug that is derived from cannabis. For example, in June 2018, the FDA approved a drug, [Epidiolex](#), that contains cannabis-derived CBD for the treatment of seizures associated with two rare and severe forms of epilepsy. That approval was based on adequate and well-controlled clinical studies, which gives prescribers confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.

It should also be noted that some foods are derived from parts of the hemp plant that may not contain CBD or THC, meaning that their addition to foods might not raise the same issues as the addition of drug ingredients like CBD and THC. We are able to advance the lawful marketing of three



such ingredients today. We are announcing that the agency has completed our evaluation of three [Generally Recognized as Safe](#) (GRAS) notices related to hulled hemp seeds, hemp seed protein and hemp seed oil and that the agency had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for these uses without food additive approval, provided they comply with all other requirements and do not make disease treatment claims.

Given the substantial public interest in this topic and the clear interest of Congress in fostering the development of appropriate hemp products, we intend to hold a public meeting in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to the safety of such products.

We'll use this meeting to gather additional input relevant to the lawful pathways by which products containing cannabis or cannabis-derived compounds can be marketed, and how we can make these legal pathways more predictable and efficient. We'll also solicit input relevant to our regulatory strategy related to existing products, while we continue to evaluate and take action against products that are being unlawfully marketed and create risks for consumers.

At the same time, we recognize the potential opportunities that cannabis or cannabis-derived compounds could offer and acknowledge the significant interest in these possibilities. We're committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

# FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food

## ***Constituent Update***

December 20, 2018

The U.S. Food and Drug Administration has completed its evaluation of three generally recognized as safe (GRAS) notices for hemp seed-derived food ingredients. The GRAS notices were submitted by Fresh Hemp Foods, Ltd. The agency has no questions about Fresh Hemp Food's conclusion that the following ingredients are GRAS under their intended conditions of use: hulled hemp seed (GRN765), hemp seed protein powder (GRN771), and hemp seed oil (GRN778).

Foods containing hemp seed and hemp seed-derived ingredients are currently marketed in the US. Hemp seeds are the seeds of the hemp plant, *Cannabis sativa*. Although hemp is from the same species as cannabis (marijuana), the seeds themselves do not naturally contain tetrahydrocannabinol (THC), the main psychoactive ingredient in cannabis. The hemp seed-derived ingredients that are the subject of these GRAS notices contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high".

The GRAS notices are for three different hemp seed-derived ingredients. The GRAS conclusions can apply to ingredients from other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars. Products that contain any of these hemp seed-derived ingredients must declare them by name on the ingredient list.

These GRAS conclusions do not affect the FDA's position on the addition of CBD and THC to food. As stated on [FDA and Marijuana: Questions and Answers](#), it is a prohibited act under section 301(l) of the Federal Food, Drug, and Cosmetic Act to introduce into interstate commerce a food to which CBD or THC has been added.

# THE COMMONWEALTH OF MASSACHUSETTS

EXECUTIVE OFFICE OF ENERGY AND ENVIRONMENTAL AFFAIRS



## Department of Agricultural Resources

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KARYN E. POLITO  
Lt. Governor

MATTHEW A. BEATON  
Secretary

JOHN LEBEAUX  
Commissioner

### Interim Policy Commercial Industrial Hemp Program

**Effective Date:** April 30, 2018

**Program Application:** Commercial Growers and Processors of Industrial Hemp

**Approved By:** John Lebeaux, Commissioner

**Authority:** M.G.L. c. 128, Sections 116 through 123

**Policy Number:** 2018-1

On July 28, 2017, Governor Baker signed H. 3818, An Act to Ensure Safe Access to Marijuana ("Act"), which updates the Commonwealth's laws that governs the use of marijuana. This legislation also created a distinction between marijuana, Hemp and Industrial Hemp, allowing Hemp to be grown commercially for Industrial Hemp or as part of an Agricultural Pilot Program.

Through newly added Sections 116 through 123 of M.G.L. c. 128, the Massachusetts Department of Agricultural Resources ("Department") now has the authority to oversee Hemp and Industrial Hemp within the Commonwealth of Massachusetts.

#### Purpose

This document sets forth the Department's Commercial Industrial Hemp Program ("Program" or "Commercial Industrial Hemp Program") policy ("Policy") for the 2018 growing season. The Department will consider all permitted activities under this Policy as falling under the definition of "Industrial Hemp" in M.G.L. c. 128, Section 116. All references to "Hemp" or "Industrial Hemp" in this Policy shall mean Industrial Hemp. The Policy establishes the Department's expectations related to the commercial growing and processing of Industrial Hemp and provides information on how to become a licensed Grower and Processor. During the interim Policy period the Department is focusing on licensing requirements under M.G.L. c. 128, Section 118. All proposed commercial activities related to the growing and processing of Industrial Hemp will need to obtain a license under this Policy in order to be considered in compliance with M.G.L. c. 128, Sections 116 through 123. The Department will address activities that may solely require registration at a later date and will not be issuing any registrations at this time. If there is a question as to whether a proposed activity requires a license under M.G.L. c. 128, Section 118, please contact the Department to determine whether the activity falls under this Policy.

The Department will be promulgating regulations for future growing seasons after initiating stakeholder engagement and conducting the necessary public process to solicit input before final promulgation. This Policy will remain in place until such time as regulations are promulgated. While the Act and M.G.L. c. 128, Sections 116 through 123 authorize activities related to marijuana and Industrial Hemp in the Commonwealth, both are still considered illegal by the federal government as they remain Schedule I Controlled Substances under Title 21 of the Controlled Substances Act, 21 U.S.C. § 811. The only exception is for certain activities under Section 7606 of the 2014 Farm Bill (H.R. 2642), which allows for industrial hemp research conducted through state departments of agriculture and/or universities and institutions of higher education when the state has also authorized such activities. Section 7606 does not, however, allow for any activities related to marijuana or general commercial activities related to Industrial Hemp.

## **Table of Contents**

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- I. General Information
  - A. Definitions
  - B. Approved Uses for Industrial Hemp
  - C. Application Requirements and Process for a Licensed Industrial Hemp Grower or Processor
- II. Grower Information
  - A. General Grower Information
  - B. Inspections and Testing
  - C. Post-Harvest Activities
- III. Processor Information
- IV. Enforcement

## **Key Risks and Considerations**

As noted above, while M.G.L. c. 128, Sections 116 through 123 authorize certain activities related to Industrial Hemp in the Commonwealth, such activities are still considered illegal by the federal government, with limited exceptions.<sup>1</sup>As a result, the Department encourages all potential Program participants to consider the following risks and considerations.

### **Risks**

- If you currently participate in or receive assistance from any activities or programs that are provided by the federal government or that utilize federal funds (i.e., loans, insurance, grants, management plans, etc.), you may no longer be entitled to continue or benefit from such activities or programs by virtue of engaging in activities permitted under this Policy.
- If the property on which you intend to grow your Crop is subject to an Agricultural Preservation Restriction (“APR”) that was acquired with federal funds or that contains language prohibiting activities in violation of federal law, your ability to engage in activities permitted under this Policy may be limited or prohibited, and your eligibility for technical assistance or grants may be similarly restricted.
- If the total number of acres you intend to use to grow your Crop is less than two (2) acres, you will not be afforded any zoning enforcement protections afforded to commercial agricultural activities under M.G.L. c. 40A, Section 3.
- If your Crop tests higher than 0.3% THC, you will run the risk of being subject to an order of destruction of the Crop.

### **Other Considerations**

- In order to ensure a Department-approved end use for your Crop, you will need to determine such end use prior to applying for a license and may wish to consider entering into an agreement with a Processor prior to cultivation. A Processor may also want to consider entering into an agreement with a Grower.
- Because Hemp is a relatively new Crop with limited or varied information about it, especially for cultivation in Massachusetts, you may wish to consider and think carefully about agricultural factors that may be unique to this Crop, including climate, size of acres grown, Crop loss, and soil conditions, such as high metal content.

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<sup>1</sup>Section 7606 of the 2014 Farm Bill recognizes the legitimacy of industrial hemp research conducted through state departments of agriculture and/or universities and institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 ([20 U.S.C. 1001](#))) or a State department of agriculture. It does not, however, allow for the general commercial growing of hemp or industrial hemp in the United States and views both as Schedule I Controlled Substances under Title 21 of the Controlled Substances Act.

- You should consider how the application of plant nutrients may be affected by regulations promulgated at 330 CMR 31.00.
- You should consider existing restrictions on the use of pesticides that may impact the ability to grow the Crop.
- You may wish to consider whether indoor or outdoor growing, or a combination of both, would be best suited to the type and volume of Crop required for your business needs.

All questions related to the Commercial Industrial Hemp Program or this Policy can be directed to the Department at 617-626-1700.

## **I. GENERAL INFORMATION**

### **A. Definitions**

As used in this Policy, the following words shall have the following meanings:

- Cannabidiol or CBD: One of the several compounds produced by cannabis plants that have medical effects.
- Cannabinoids: Any of several compounds produced by cannabis plants that have medical and psychotropic effects. This includes but is not limited to CBD and THC.
- Cannabinoid profile: The amounts expressed as the dry weight percentages, of delta-nine-tetrahydrocannabinol, Cannabidiol, tetrahydrocannabinolic acid and cannabidiolic acid in a Hemp product.
- Certificate: Documentation stating that the Department has sampled and tested the Crop and determined that the Crop demonstrates that it is at 0.3% THC or below.
- Commercial: Growing and/or Processing Industrial Hemp for sale. This excludes the growing of the Crop under the Agricultural Pilot Program.
- Crop: Hemp grown for the purposes of Industrial Hemp.
- Department: Massachusetts Department of Agricultural Resources.
- Extractor: A Processor that creates Industrial Hemp products from the Hemp plant. The Extractor will produce items such as fiber, seed, or oil from the plant.
- Grower: A person that cultivates Industrial Hemp.
- Harvest Form: A form required at least fourteen (14) days prior to harvest which includes location, variety and amount of Hemp produced, and an expected harvest or destruction date, whichever is applicable, and which allows the Department to coordinate with the Grower to schedule the required inspections and sampling required by M.G.L. c. 128, Section 122.
- Hemp: The plant of the genus cannabis and any part of the plant, whether growing or not, with a delta-9-tetrahydrocannabinol concentration that does not exceed 0.3 per cent on a dry weight basis or per volume or weight of marijuana product or the combined per cent of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid in any part of the plant of the genus cannabis regardless of moisture content.

- **Industrial Hemp:** Hemp that is used exclusively for industrial purposes including, but not limited to, the fiber and seed. The Department will consider all permitted activities under this Policy as falling under the definition of “Industrial Hemp” in M.G.L. c. 128, Section 116. All references to “Hemp” or “Industrial Hemp” in this Policy shall mean Industrial Hemp.
- **Manufacturer:** A Processor that creates an end product that is packaged, labeled and ready for sale from Industrial Hemp including but not limited to cloth, infused products, building products, and edibles
- **Person:** A natural person, corporation, association, partnership or other legal entity.
- **Planting Form:** A form, required no later than ten (10) days after planting, that indicates the location, variety, source, intended use, and expected harvest date of the Crop along with an inventory of any remaining Hemp seeds that were not planted after acquisition, and associated plans for storage or transfer to another licensed Program participant.
- **Processor:** A person that converts Industrial Hemp into a marketable form, including through extraction or manufacturing.
- **THC:** Delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid.
- **Volunteer Plant:** Any cannabis plant which grows of its own accord from seeds or roots in the years following an intentionally planted cannabis crop. Volunteer plants are not intentionally planted.

## **B. Approved Uses for Industrial Hemp**

Pursuant to M.G.L. c. 128, Section 117(c), Industrial Hemp shall only be used for the following: (i) research purposes; and (ii) Commercial purposes considered reasonable by the commissioner. The Department considers the following uses for Industrial Hemp as reasonable:

- Fiber
- Seed
- Hemp seed oil
- Cannabidiol (CBD) that is derived from a Crop that is certified by the Department as Industrial Hemp
- Seed for cultivation
- Seed, seed meal, and seed oil for consumption
- Other reasonable Commercial purposes approved in advance by the Department as consistent with the purposes of M.G.L. c. 128, Sections 116 through 123.

If a Grower or Processor would like to use Industrial Hemp for a purpose not listed in this Policy, the Grower must submit a written request for that use to the Department prior to engaging in the proposed use. The Department will review the request and make a written determination as to whether the proposed use satisfies this Policy.

## **C. Application Requirements and Process for a Licensed Industrial Hemp Grower or Processor**

At this time, any Person proposing to engage in the planting, growing, harvesting, possession, processing or selling of Industrial Hemp must obtain a license issued by the Department, depending on the type of activity.

## Licenses

1. Licenses are required for both Growers and Processors prior to engaging in any activity authorized by M.G.L. c. 128, Sections 118 through 123 or this Policy. A Grower is defined as a Person who is cultivating the Crop and Processors are separated into two different categories: Extractor; and/or Manufacturer. Each applicant for a Commercial Industrial Hemp Grower or Processor license shall submit to the Department, in a form and manner determined by the Department, a complete application, which includes the following information:
  - i. Full name and address of applicant(s);
  - ii. Name and address of the Industrial Hemp operation;
  - iii. GPS coordinates provided in decimal degrees taken at the approximate center of the growing field or building entrance; A map of the growing or processing area illustrating clear boundaries;
  - iv. If Industrial Hemp is cultivated in a field, the area in acres of each field;
  - v. If Industrial Hemp is cultivated in a greenhouse or other building, the approximate dimension or square feet of the growing area
  - vi. Written consent by the applicant to the Department to conduct inspections, sampling, and testing under the terms of this policy;
  - vii. A non-refundable application fee in an amount which shall be established by the commissioner and;
  - viii. Any other information reasonably requested by the Department to fulfill its oversight obligations pursuant to M.G.L. c. 128, Sections 118 through 123.

In addition to the application form, each applicant shall submit a nonrefundable application fee. If the application fee does not accompany the application, the license application will be deemed incomplete and will not be processed until such time as the fee is received. If an application is approved, an additional license fee shall also be required prior to issuance of a Grower or Processor license. All licenses will expire on December 31<sup>st</sup> of the year it was issued.

Upon the approval of an application for a Grower or Processor license, the Department will notify the state police as well as local police in the municipality where the Crop will be grown. This notification will include the address and GPS coordinates of the Crop. The Department will also notify the chief administrative or executive officer<sup>2</sup> in the municipality where the Crop will be grown or processed in order to answer any questions or concern that they may have relative to the program. The licensee's address and security schematic or global positioning system coordinates that are provided to the chief administrator/executive offer and police shall not be subject to public disclosure as set forth in M.G.L. c 128, Section 118 and any transmittal of this information from the Department shall include the fact that it is exempt from public disclosure by statute.

2. Grower/Processor Dual License: A Person proposing to participate in growing and processing activities may apply for a Grower/Processor license and fill out the appropriate application form and submit the appropriate application and license fees.

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<sup>2</sup> "Chief administrative officer," when used in connection with the operation of municipal governments, shall include the mayor of a city and the board of selectmen in a town unless some other local office is designated to be the chief administrative officer under the provisions of a local charter... 'Chief executive officer', when used in connection with the operation of municipal governments shall include the mayor in a city and the board of selectmen in a town unless some other municipal office is designated to be the chief executive officer under the provisions of a local charter." *See* M.G.L. c. 4, Section 7.

Fee Schedule applicable to Grower and Processor Licenses<sup>3</sup>

Industry	Type	Fee
Grower	License Application Fee	\$100 non-refundable (annual)
Processor (Extractor, Manufacturer or both)	License Application Fee	\$100 non-refundable (annual)
Grower & Processor	License Application Fee	\$100 non-refundable (annual)
Grower	License	\$300 (annual)
Processor	License	\$300 (annual)
Grower & Processor	License	\$500 (annual)

3. Approval/Denial of license application; Renewal

Pursuant to M.G.L. c. 128, Section 119, the Department shall grant or deny a license application after reviewing and ensuring all statutory and Policy requirements have been met. Any applicant denied a license or license renewal may appeal no later than twenty one (21) days after receipt of the notice of the licensure action pursuant to M.G.L. c. 128, section 123. A request for an appeal should be submitted in writing to the Department. An adjudicatory hearing shall be conducted in accordance of M.G.L. c. 30A.

4. Approval

If approved, the Department may issue a license that will contain, at a minimum, the following:

- Full name and address of the applicant(s);
- Name and address of the Industrial Hemp operation;
- Department issued license number;
- Signature of Department representative;
- A written finding that the Grower/Processor has complied with M.G.L. c. 128, Section 116-123 and licensure is in the best interest of the Commonwealth; and
- Expiration date (all licenses will expire on December 31<sup>st</sup> of the year issued).

In the event of any material change to the information provided to the Department in the license application, including the growing location, the Licensee shall immediately notify the Department. Once notified, the Department will review the change to determine whether a new license application or an amendment to an existing license will be required. A licensee shall not implement any proposed changes without prior written approval from the Department.

5. Denial

Pursuant to M.G.L. c. 128, Section 119(b), the Department “shall deny an application for a license filed pursuant to section 118 if the applicant: (i) fails to satisfy the minimum qualifications for licensure pursuant to sections 116 to 123, inclusive; or (ii) for good cause shown.” Good cause to deny an application may include, but not be limited to the following: failure to comply with this Policy or other statutes or regulations that govern the operation, problematic site location, or failure to provide additional information reasonably requested by the Department.

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<sup>3</sup> These fees will be promulgated as part of 801 C.M.R. 4.00, in consultation with the Executive Office for Administration and Finance. Until further notice, applicants shall pay the fees listed above.



## 6. Renewal

All Growers and Processors will be required to submit a license renewal application prior to the expiration date of their current license. In order to ensure that the Department has ample time to review and issue the renewal, renewal applications must be submitted to the Department between October 1<sup>st</sup> and November 15<sup>th</sup>. The Department will review all renewal applications in accordance, with M.G.L. c. 128, Sections 116 through 123 and all regulations, policies, and guidance that may be in effect at the time the renewal application is submitted. The Department will also evaluate the Grower or Processors previous participation with the Program. The Department may deny a renewal under the Section 119(b) if it determines the Grower or Processor have not complied with this Policy or other statutes or regulations that govern the operation.

# II. GROWER INFORMATION

## A. General Grower Information

### 1. Seed Acquisition

Pursuant to M.G.L. c. 128, Section 117(b) (ii), a Grower shall only acquire Hemp seeds from a distributor that has been approved by the Department. The Department shall deem a distributor to be an “approved distributor” if it:

- Produces certified seeds that contain no more than 0.3% THC; and
- Provides documentation to the Grower showing THC levels are no more than 0.3% at the time the seed is received by the Grower.

An applicant for a Growers license will be required to certify that they agree to obtain seed with the necessary documentation and to provide this documentation to the Department prior to planting the Crop, or otherwise upon request.

The Department may require that a distributor provide additional information before the distributor is approved to distribute seeds in the Commonwealth

A Grower may not obtain seeds without first obtaining a license issued by the Department.

### 2. Sign Posting

- a. A Grower must post a Department-approved sign at conspicuous points of entry to the area (greenhouse/field) where the Crop is grown. If there is more than one point of entry, a Grower must post a sign every 200 feet.
- b. Signs should be at least fourteen (14) inches by sixteen (16) inches with letters one (1) inch high and contain, at a minimum, the following:
  - i. Statement “*Crop grown in this field is Industrial Hemp that is licensed by the Massachusetts Department of Agricultural Resources pursuant to M.G.L. c. 128, Sections 116-123.*”;
  - ii. Department issued license number;
  - iii. Emergency contact information (Name and phone number); and
  - iv. Department contact information: (617) 626-1700.

### 3. Reporting of planting information to the Department

- a. Upon the Grower receiving the seed, the Grower must provide the Department with a copy of the seed certification obtained from the seed distributor demonstrating that the seed is at or below the 0.3% THC level.
- b. No later than ten (10) days after planting of the Crop, the Grower must submit the Department approved Planting Form to the Department.

## **B. Inspection and Testing**

The Department is authorized to conduct inspections and testing to ensure compliance of all activities authorized under M.G.L. c. 128, Sections 116 through 123. This includes compliance with the Policy as well as testing to ensure that THC levels of the Crop meet the limitations set by M.G.L. c. 128, Section 116.<sup>4</sup>

### **1. Inspections**

- a. All Growers are subject to testing and inspections of Crops. The Department will make every effort to provide advanced notice of testing and inspections to the Grower unless such notice would impact the Department's ability to conduct necessary enforcement activities authorized by M.G.L. c. 128, Sections 116 through 123. Inspections will occur at the following stages:
  - i. License application process: Prior to issuing a license, the Department may schedule a site visit to the property. The purpose of this visit will be to review information that was provided during the application process and to also ensure a better understanding of the growing operation.
  - ii. Routine Sampling: The Department will test the Crop in order to ensure that the Crop does not exceed the 0.3% THC level, as required by the M.G.L. c. 128, Section 116. Sampling shall be conducted for all licensees prior to harvest and with the Grower present. Routine sampling will be scheduled in advance with the Grower or an authorized representative of the Grower
  - iii. Record Inspections: The Department may conduct routine record inspections to ensure that the Grower is maintaining all necessary information. This may include plant nutrient applications (330 CMR 31.00) and any other record keeping required by law.
  - iv. Follow up Inspection: The Department may conduct follow up inspections in order to determine if information provided by the Grower is true and accurate. This follow up may include planting and harvesting observations; sampling of the Crop; or additional record reviews. These inspections may be announced or unannounced.

### **2. Testing**

- a. The Grower shall contact the Department no later than fourteen (14) days prior to harvest of the Crop or any portion of the Crop to schedule sampling for testing.
  - i. The Department will collect samples of the Crop and bring material to a Department-approved lab for testing. The Grower or an authorized representative of the Grower must be present during the sampling.
  - ii. The Grower shall harvest within ten (10) days of the collection of samples, unless otherwise authorized in writing by the Department. If harvesting after collection of samples but prior to receiving the sample results, the Grower must hold onto all harvested Crop material until a Certificate is issued from the Department.
  - iii. The Grower shall submit the Department approved Harvest Form to the Department within ten (10) days of harvest.
  - iv. If sample results show THC levels do not exceed 0.3% then a Certificate will be issued by the Department to the Grower. Upon receipt of a Certificate, the Grower may move the Crop off the licensed site if needed for processing or sale.

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<sup>4</sup> M.G.L. c. 128, Section 122 provides that "[t]he department may inspect and have access to the equipment, supplies, records, real property and other information deemed necessary to carry out the department's duties under sections 116 to 123, inclusive, from a person participating in the planting, growing, harvesting, possessing, processing, purchasing, selling or researching of hemp, industrial hemp. The department may establish an inspection and testing program to determine delta-9 tetrahydrocannabinol levels and ensure compliance with the limits on delta-9 tetrahydrocannabinol concentration."

- v. If sample results show THC levels exceed 0.3%, then the Crop is no longer considered Hemp and the Grower is prohibited from harvesting the Crop for Commercial purposes or engaging in any other activities under this Policy. The Grower may also be subject to civil or criminal liability under state and federal marijuana laws. The Grower may opt for a second round of sampling at his/her own cost. If the second round of sampling of the Crop show THC levels higher than 0.3%, then the Grower may opt for a third round of sampling of the Crop while still in the ground or harvested Crop at his/her own cost. In the event that testing results show THC levels higher than 0.3%, the Grower will be instructed to destroy the Crop. The Grower and Department will enter into a written agreement setting forth the terms of such resolution and the Department will be present for the harvest and disposal of any Crop that does not comply with M.G.L. c. 128, Sections 116 through 123.

### 3. Pesticide Use

The Department is charged with regulating pesticide use in the Commonwealth under M.G.L. c. 132B. The Department does not register any product that is not already registered by the United States Environmental Protection Agency (“EPA”). Currently, EPA does not allow the use of a registered pesticide on marijuana or hemp. There are products that are exempt from EPA registration as these products or the ingredients within them are considered minimum risk by EPA. Please refer to the following EPA website to find a list of products and active and inert ingredients that are exempt from registration:

<https://www.epa.gov/minimum-risk-pesticides>. The Department does not approve or provide for the registration of products for use on marijuana, including Hemp.

In the event a Grower uses a pesticide in violation of M.G.L. c. 132B or the regulations promulgated thereunder at 333 CMR 2.00 through 14.00, they may be subject to enforcement action by the Department.

### 4. Energy Efficiency and Environmental Standards

Until such time that the Department issues its own policy on energy efficiency and environmental standards, any indoor facility used for Industrial Hemp cultivation, including greenhouses, must comply with guidelines issued by the Cannabis Control Commission, in consultation with the working group established under section 78(b) of the Act. If the Commission has not adopted guidelines by the time a Grower license is approved by the Department, the Grower is responsible for reviewing and understanding any guidelines that are adopted after that time. The Grower must ensure compliance with such guidelines, or other Department policies, issued by the time of the Grower’s application for license renewal.

## **C. Post-Harvest Activities**

### 1. Transport of Crop

Only a Grower or Processor licensed by the Department may transport Industrial Hemp and no Crop, or any portion thereof, may be transported without a copy of the Certificate issued by the Department. The Licensee must ensure that this Certificate stays with the Crop at all times and accompanies all shipments of the Crop, including any portion, so that anyone coming into contact with the Crop has access to written documentation demonstrating that the Crop was grown in compliance with M.G.L. c. 128, Section 116 and this Policy.

### 2. End of the year reporting

The Grower shall submit an end-of-year report, on a form prescribed by the Department, with their renewal application or December 1<sup>st</sup> if not applying for renewal for the following year to the Department indicating, at a minimum, the following information:

- i. Variety Grown
- ii. Purpose of Crop

- iii. Harvested amount
- iv. End destination or use of Crop
- v. Volunteer Plants, if any occurred and how they were managed

### 3. Volunteer Plants

It shall be the responsibility of the license holder to monitor and destroy Volunteer Plants that are discovered outside of the licensed growing area.

## III. PROCESSOR INFORMATION

Processors are divided into two different categories based upon their activities:

- **Extractor:** Processor that removes Industrial Hemp from the plant. The Extractor will produce items such as fiber, seed, and oil from the plant.
- **Manufacturer:** Processor that creates an end product that is packaged, labeled and ready for sale from Industrial Hemp such as but not limited to cloth, infused products, building products, and edibles.

There are different duties and responsibilities as described below depending on the type of Processor activity. A Processor can be both an Extractor and a Manufacturer. A Processor may only take Industrial Hemp from a Massachusetts licensed Grower, unless otherwise authorized by federal law. The Department will require documentation demonstrating that such federal authorization is permitted.

### 1. Duties and Responsibilities of the Extractor:

- a. An Extractor may only receive Crops from a Massachusetts licensed Grower.
- b. The Crop must have the Department issued Certificate accompanying the Crop, which certifies that the Crop does not exceed 0.3% THC.
- c. At the time of the receipt, the Extractor must assign the Crop a lot number that corresponds with Grower information such as name, address, contact information and maintain records relative to the receipt of the Crop. The records shall include, but not be limited to:
  - i. Date of receipt
  - ii. quantity received
  - iii. Grower information, including name, address of fields that were grown on, license information and contact information.
  - iv. Copy of the Certificate
  - v. Lot number assigned by Extractor
- d. An Extractor shall keep records for each batch processed. The records shall be kept for a minimum of three (3) years and shall include, but not be limited to:
  - i. Date of extraction
  - ii. Batch number, including the lot number
  - iii. Type of extraction method
  - iv. Amount extracted
  - v. What was extracted (grain, seed, fiber, oil, CBD)
  - vi. Lab testing results

### 2. Testing Requirements for the Extractor

- a. If the Crop will be used for human consumption or absorption (including but not limited to, inhaling, eating, drinking, swallowing or topical application), the finished extraction must be tested at the times required by and for the following in accordance with Department of Public Health ("DPH") testing protocol ("Protocol")<sup>5, 6</sup>:

<sup>5</sup><https://www.mass.gov/files/documents/2017/12/20/105cmr725.pdf>

- i. Cannabinoid profile
    - ii. Solvents
    - iii. Pesticides
    - iv. Metals
  - b. All testing is the responsibility of the Extractor and must be done at a lab that has been registered by DPH to perform such testing<sup>7</sup>.
  - c. All lab results must be sent to the Manufacturer with the finished extracted product.
  - d. The Extractor shall send all lab reports to the Department within seven (7) business days of receipt of the results.
  - e. If test results for the finished extraction exceed the limits set forth in the Protocol, then the finished extraction shall not be used in any product for human consumption or absorption. The Extractor therefore shall not sell the finished extraction to any Manufacturer or any other entity, or otherwise sell or use the extraction for human consumption or absorption. Instead, the Extractor may either destroy the product or work with the Department to find an alternate use for the finished extraction. Should an alternate use be found, the Extractor will enter into a written agreement with the Department setting forth the terms of any such resolution.
3. Duties and Responsibilities of the Manufacturer
- a. The Manufacturer shall only receive extracted product (such as oil, seed, and fiber) from a Massachusetts licensed Extractor
  - b. At the time of the receipt, the Manufacturer shall assign the extracted product a lot number and maintain records relative to the receipt of the extracted product. The records shall be kept for a minimum of three (3) years and include, but not be limited to:
    - i. Date of receipt
    - ii. Amount received
    - iii. Extractor or Grower information including name, license number, and contact information.
    - iv. Lab results indicating cannabinoid profile, solvents, pesticides and metals
    - v. Extractor assigned batch and lot number
  - c. When the Manufacturer produces an end product, records shall be kept for a minimum for three (3) years for each batch of the end product. The records shall include, but not be limited to:
    - i. Date of production
    - ii. Batch number (must include lot number)
    - iii. Amount produced
    - iv. Name of product
4. Labeling Requirements for the Manufacturer
- a. Manufacturers shall ensure that any products that will be used for human consumption and absorption (including but not limited to inhaling, eating, drinking, swallowing or topical application), are labeled in clear, legible wording no less than 1/16 inch in size on each container.

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<sup>6</sup><https://www.mass.gov/service-details/medical-use-of-marijuana-program-product-testing>

<sup>7</sup><https://www.mass.gov/files/documents/2017/12/20/mmj-laboratory-registration-policy.pdf>

- b. Labels shall be firmly affixed and shall include the following:
  - i. Manufacturer name, license number and address
  - ii. Cannabinoid profile (Must include THC and CBD concentrations, if any)
  - iii. Batch number
  - iv. Statement *“This product is derived from Industrial Hemp.”*
  - v. Statement *“This product has not been analyzed or approved by the FDA.”*
  - vi. Statement *“This product derived from Industrial Hemp has not been tested or approved by the Massachusetts Department of Agricultural Resources.”*

## **IV. Enforcement**

The Department will make every effort to work with Growers and Processors to provide compliance assistance. However, it is the responsibility of the Grower or Processor to review and understand M.G.L. c. 128, Sections 116 through 123 and this Policy. Failure to comply with the Department’s requirements under this Policy may result in revocation or denial of a license. In addition, failure to comply with the requirements may result in the issuance of fines. An entity has the right to appeal any enforcement action under M.G.L. c. 128, Section 123.

Pursuant to M.G.L. c. 128, Section 123, “[t]he department may establish civil administrative fines for violations of sections 116 to 123, inclusive. A person aggrieved by the assessment of a fine under this section or a licensure action under section 120 may appeal by filing a notice of appeal with the department not later than 21 days after the receipt of the notice of the fine or licensure action. The adjudicatory hearing shall be conducted in accordance with chapter 30A.”

The Department will determine the amount of any fines imposed based on the nature of the violation, and considering all relevant factors including the ability for the violation to be corrected, severity of the violation, willfulness, impact to public health and safety.